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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,850	03/31/2004	Govindan Rajamohan	U 015118-6	5613

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EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
07/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,850	RAJAMOHAN ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *3 and 10-25* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *2, 4-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Amendment of May 7, 2007 is acknowledged. Claims 1-6 have been amended. Claims 1-25 are pending in the application. Claims 1-2 and 4-9 are under examination.

DETAILED ACTION

Formal matters

The examiner acknowledges the Statement of Biological Culture Deposit filed May 7, 2007. The statement as scanned in the PTO records misses BP/4 form of Budapest Treaty on The International Recognition of the Deposit of Microorganisms for the Purposes of the Patent Procedure in case of *E. coli* MTCC05148 and plasmid pOXYSAK-2. Please file the missing form.

Objections

1. In the Office action of Jan. 30, 2007 (previous action) claims 4-6 were objected to as directed to plasmids having "International Deposition No. BPL-0019" whereas the correct deposit numbers for the plasmids are Deposit No. E. coli of claims 7-9". The plasmids cannot be deposited under Budapest Treaty, only organisms. What applicants call International Deposition No. BPL-0019 to No. BPL-0021 may refer to an Indian national deposit of plasmids made with Microbial Type Culture Collection & Gene Bank in Chandigarh, India. Thus far Applicants have not filed any documents related to the deposit of plasmids having depositions number BPL-0019 to BPL-0021. Thus, the claimed plasmids, as evidenced by the forms PB/4 and PB/9 of Budapest Treaty on The International Recognition of the Deposit of Microorganisms for the Purposes of the Patent Procedure, are comprised by deposited E. coli No.5146- No. 5148. Please correct page 4 of the specification to reflect the fact.

2. Figures 10 and 11 are incomprehensible. Please align sequences properly, with names on the left side.

3. In the specification, page 5, the steps of the method are not marked by letters by which they are referred to in the text.

4. Claim 3 is objected to because it is directed to a peptide sequence of SAK-1 gene of SEQ ID NO: 3. A gene is a nucleotide sequence and not a peptide sequence. In addition the term amino acid sequence seems to be more proper.

Rejections

Rejections not repeated below are withdrawn, due to amendments.

35 USC 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is confusing as directed to a peptide sequence of SAK-2 gene of SEQ ID No:3. SEQ D NO:3 is an amino acid sequence encoded by recombinant modified gene called SAK-2, which is identified by SEQ ID NO: 2. It is assumed for examination purposes that Claim 3 is directed to the amino acid sequence of SEQ ID NO: 3.

35 USC 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; Diamond v. Chakrabaty, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified

protein or nucleic acid". It should be noted that a recombinant enzymes/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

35 USC 112 first paragraph

Claims 4-6 remain rejected for lack of written description of the plasmids towards which they are directed. Please amend the claims as follows.

"Claim 4. A plasmid pRM1 contained in E. coli of International Deposition No. 5146 in the Microbial Type Culture Collection at Institute of Microbial Technology, Chandigarh, India", and please amend claims 5 and 6 accordingly.

Claims 2, 5, 6 and 8-9 are rejected because they are directed to DNA molecules and cells transformed with said DNA molecules that lack proper written description of structure. Particularly, claim 2 is directed to SAK-2 gene of SEQ ID NO: 2 encoding protein of SEQ ID NO: 3. The nucleotide sequence of SEQ ID NO: 2 consists of 582 nucleotides according to sequence listing and does not contain a stop codon. However, it is only 581 nucleotides long according to Fig. 6. Furthermore, SEK-2 protein is according to sequence listing 363 amino acids long, thus it may not be encoded by a nucleotide sequence that is 581 or 582 nt long. Furthermore, the first three codons of SEQ ID NO: 2 are Gly, Leu, and Lys, whereas the three first amino acids of SEQ ID NO: 3 are Glu, Ala and Leu.

SAK-1 gene is not claimed by its sequence that is 606 nt long according to Fig. 5, nevertheless it seems that DNA of SAK-1 is set forth by SEQ ID NO: 9. SEQ ID NO: 9 seems to encode protein of SEQ ID NO: 10, which is 377 amino acid long! All these discrepancies are very confusing if one takes into account that the enzyme as known for tens of years is 136 amino acid long, and in addition, applicants' intention was to modify its N terminus, particularly residues 6 and 8, to expressed it efficiently in E. coli. As such, SEQ ID NOs: 2, and 3, as well as SEQ ID NO: 9 which supposedly is contained in the plasmid pOXYSAK-1, are not described as encoding SAK.

In conclusion, one having skills in the art is not convinced that applicants were in possession of the claimed invention at the time the application was filed.

35 USC section 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sako T. et al. (Cloning and expression of the staphylokinase gene of Staphylococcus aureus in Escherichia coli, Mol. Gen. Genet. 190, 271-277, 1983).

Claim 4 is directed to a plasmid comprising the gene of S. aureus encoding natural staphylokinase. Claim 7 is directed to a recombinant E. coli comprising said plasmid.

Sato et al. cloned the SAK gene from its natural host S. aureus, and after inserting it into plasmid pBR322 transfected it into E. coli.

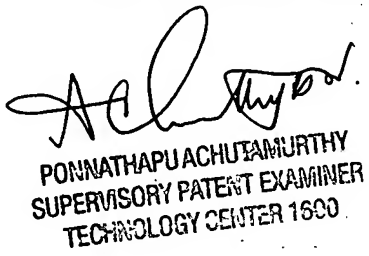
It would have been obvious to have the SAK gene of S. aureus disclosed by Sako et al. and insert it into any publicly available plasmid that allows its expression in E. coli, for example with plasmid ET96b produced commercially by PROMEGA, WI USA. It would also have been obvious to transfect E. coli with the plasmid for production of SAK protein.

The probability of success is 100%, because Sako at al. proved it. The motivation is provided by Sako et al. who teach that the enzyme is one of plasminogen activators used in clinics. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made, and was as a whole *prima facie* obvious.

Conclusion

Claim 1 is allowed as directed to the expression cassette of SEQ ID NO: 1 that is novel. Claims 2, and 4-9 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner